

**Informational Briefing on CropLife Concerns: Good Laboratory Practice (GLP)
Inspection History and Pesticide Certificates of Origin/Establishment
11/15/18**

Action Needed:

Ex. 5 Deliberative Process (DP)

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Current Issue 1: CropLife received misinformation from one of its members saying OECA management directed staff to stop responding to requests confirming a laboratory's GLP compliance history. OECA management did not direct anyone to stop responding to GLP requests from industry. In fact, staff are expected to reply in a timely manner to any such request.

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Background:

- EPA's most recent letter issued confirming the GLP compliance history of a laboratory was provided to Dow Agrosiences on October 17, 2018 (attached "Morocco" letter).

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- **Ex. 5 Deliberative Process (DP)**

Current Issue 2: CropLife is asking EPA to reconsider a decision to stop issuing "Certificates of Origin" and "Certificates of Establishment" to industry regarding pesticides manufactured in the US and exported to other countries. CropLife says the certificates are needed to support US export business and combat counterfeits.

Background:

- Some countries require a "Certificate of Origin" (CO) or a "Certification of Free Sale" (CFS) in the exporting country before they will accept certain types of

products. Exporters of foods, drugs, and animal (or other agricultural) products must provide these documents on a regular basis.

- A CO is normally provided by the exporter, sometimes through a state or local chamber of commerce.
- A CFS is an official document from the government of a country of export that certifies that domestic laws and regulations allow sale of the exported product. USDA and HHS both have procedures (including fees) for issuing these certificates for products within their regulatory jurisdictions.
- There is no provision in FIFRA regarding COs or CFSs for export of pesticides. EPA regions used to provide as a courtesy a letter to companies that “certified” the registration of a production establishment based on data collected under FIFRA Section 7. After searching online, and asking registrants, EPA has been unable to verify how such letters can satisfy requirements of importing countries.
- EPA/OPP issues certificates of U.S. registration, or “Gold Seal Letters,” for registrants who need proof of the legal status of their pesticides. There is a PRIA fee-for-service for providing these letters.
- Over time most regions stopped issuing “Certificate of Origin” letters as they do not have the information to “certify” the origin of a pesticide, whether registered or unregistered, arriving at a foreign destination. Regions switched to issuing a “Certificate of Establishment” letter which simply confirmed the active registration status of a pesticide producing establishment with EPA based on data in the Section Seven Tracking System (SSTS).

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Recommended National Approach:

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